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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/692,011 | 10/24/2003 | Kenji Nakajima | Q78108 | 8536 |

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

LUM, LEON YUN BON

ART UNIT PAPER NUMBER

1641

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/692,011 | Applicant(s) NAKAJIMA, KENJI | |
| | Examiner Leon Y. Lum | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1, 4, 7, 10 and 13-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 5, 6 and 8-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed February 1, 2006 is acknowledged and has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 2-3, 5-6, 8-9, and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al (US 6,716,629 B2) in view of Clark et al (US 5,358,691).

Hess et al reference teaches the step of providing a platen (biochemical analysis unit; base plate) with an array of through-holes traversing the platen, the through-holes having a three-dimensional hydrophilic scaffold placed therein (i.e. porous adsorptive

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regions comprising holes filled with a porous material), and wherein the scaffold is activated to couple biological materials within the holes (i.e. bound receptors). See column 13, line 65 to column 14, line 3; and column 20, lines 45-62. In addition, Hess et al teach that platen can be used to screen for ligands by affinity (i.e. performing a specific binding detection process) by performing the step of applying pressure across the platen to create a flow of sample through the array of through-holes, where the sample is a second set of reagents that can react with reagents already loaded into the through-holes (i.e. forcibly causing a ligand to flow through the holes; ligand subject to specific binding with bound receptors). See column 35, lines 32-42; and column 28, lines 16-22. Furthermore, Hess et al teach that specific binding can be detected by applying a radiolabeled sample protein to an array of 100,000 different proteins in the platen, applying a wash step, and then detecting the presence of radiolabeled protein by a phosphor-imaging system (i.e. detecting the receptor by the utilization of a labeling substance; labeled receptor). See column 55, line 64 to column 56, line 7. Hess et al also teach that all through-holes can be loaded (i.e. through each of the holes). See column 7, lines 14-15.

However, Hess et al fail to teach the step of performing a bubble removing or dissolving process during the flowing of the liquid.

Clark et al reference teaches the step of automatically flushing bubbles out of a fluidics system, in order to prevent the presence of air bubbles from affecting the precision and accuracy of the dispenser. See column 21, lines 7-48.

It would have been obvious to one of ordinary skill in the art to modify the method of Hess et al with the step of automatically flushing bubbles out of the fluidics system, as taught by Clark et al, in order to prevent the presence of air bubbles from affecting the precision and accuracy of the dispenser. The advantage of providing more accurate dispensing of solution provides the motivation to combine the bubble extracting step of Clark et al in the method of Hess et al. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in including the bubble extracting step of Clark et al in the method of Hess et al, since Hess et al teach the step of dispensing fluid into an array, and the bubble extracting process of Clark et al would provide a more effective way of dispensing the fluid.

With respect to claims 11-12, Hess et al teach that nucleic acids can be labeled with an enzyme (i.e. auxiliary substance-bound receptor) such as horseradish peroxidase and then incubated with a substrate that produces a luminescent, fluorescent, or chromogenic signal upon reaction with the enzyme flowing binding and washing steps (i.e. causing a labeling substance to bind to the auxiliary substance, and detecting the auxiliary substance bound receptor by utilization of the labeling substance). See column 36, lines 2-9.

Response to Arguments

5. The obvious-type double patenting rejection made in the previous Office Action has been withdrawn due to the instant amended claims.

6. Applicant's arguments with respect to claims 2-3, 5-6, 8-9, and 11-12 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. No claims are allowed.

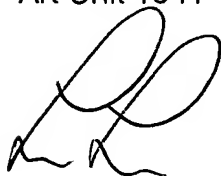
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y. Lum
Patent Examiner
Art Unit 1641



LYL


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
04/14/06